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SUBJECT: CROATIA SPECIAL 301 REVIEW

REF: A) STATE 14937

B) 05 ZAGREB 1721

¶1. Summary and Recommendation: Croatia's intellectual property (IP) protection regime is generally adequate and in accordance with accepted standards. However, problems in the area of patent protection for pharmaceuticals continue. Unfortunately, the GOC has done nothing in the last year to resolve this issue, despite our continued pressure. Although pharmaceutical patent infringement is an anomaly within Croatia's IP regime, post recommends that Croatia remain on the Special 301 Watch List. We do not believe, however, that this problem is of sufficient gravity to warrant moving Croatia to the Priority Watch List, as industry has recommended. End Summary and Recommendation.

Pharmaceutical Protection Weak

¶2. Croatia's main weaknesses in IP protection are in patent linkage (see ref B) and inconsistent enforcement of the bilateral memorandum of understanding (MOU) on data exclusivity. Post has worked consistently over the past year to urge the GOC to implement some form of patent linkage to prevent marketing authorization from being given for generic copies of drugs that are still protected by a valid patent in Croatia. Unfortunately, the GOC has not yet acted to address this problem, although we are hopeful that pressure brought to bear in Croatia's EU accession negotiations could prove instrumental in finally bringing about a resolution in the near term.

¶3. Croatia's implementation of data exclusivity legislation in late 2004 was a significant, if imperfect, step forward in tightening IP protection for pharmaceuticals. Enforcement of the MOU, however, appears to be inconsistent. Post was made aware of one instance where the state drug agency was on the verge of issuing marketing authorization for a compound still protected by 6-year data exclusivity in Croatia. Authorization was ultimately withheld following post's intervention with the health ministry.

301 Recommendation

¶4. Although we do not believe that either of

these problems is endemic or indicative of overall weakness in Croatia's IP protection regime, we nevertheless recommend that Croatia remain on the Special 301 Watch List. Despite the relatively narrow scope of the problem, removing Croatia from the Watch List would send the wrong signal about the seriousness of the 301 process. However, we do not believe that Croatia should be moved to the Priority Watch List, as PhRma has recommended.

¶5. Post is aware of the other concerns raised by PhRMA concerning market access and reimbursements for pharmaceutical products. Although we are sympathetic to these problems and urge the GOC at every opportunity not to jeopardize public access to innovative drugs, we do not believe that this is an IP issue that should be factored into the 301 decision on Croatia.

Other Developments

¶6. Croatia is currently undergoing "screening" on IP protection as part of its EU accession negotiations. In November, the GOC released a new National Strategy for IP protection in an effort to bring Croatia's laws into conformity with the EU acquis.

¶7. In general, Croatia's enforcement of IP laws is good. Nevertheless, piracy remains a constant problem, with police and customs officials making regular seizures of pirated audio and video material. Software piracy remains common among private users, although business and industry generally use legal copies.

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